

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

J M SMITH CORPORATION d/b/a, SMITH DRUG
COMPANY, on behalf of itself and all others similarly
situated,

Plaintiff,

v.

ACTAVIS, PLC, FOREST LABORATORIES, LLC,
MERZ GMBH & CO. KGAA, MERZ PHARMA
GMBH & CO. KGAA and MERZ
PHARMACEUTICALS GMBH

Defendants.

No. 15-cv-7488-CM

**MEMORANDUM IN SUPPORT OF DIRECT PURCHASER PLAINTIFFS'
MOTION TO STRIKE (OR DISREGARD) DEFENDANTS' REFERENCE TO
EXTRINSIC MATERIAL, AND FOR LEAVE TO FILE A SUR-REPLY IN FURTHER
OPPOSITION TO DEFENDANTS' MOTION TO DISMISS DIRECT
PURCHASER PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT**

TABLE OF CONTENTS

TABLE OF CONTENTS.....	ii
TABLE OF AUTHORITIES	iii
I. INTRODUCTION.....	1
II. ARGUMENT	1
A. Defendants’ Extraneous Declaration and Exhibits Should Be Stricken From the Record and Disregarded	1
B. If the Court Considers Defendants’ Extraneous Material, It Should Give Plaintiffs Notice of Its Intention to Convert Defendants’ Motion into One for Summary Judgment and an Opportunity to Submit Further Evidence, or a Rule 56(d) Declaration	5
C. Plaintiffs Should Be Granted Leave to File a Sur-Reply to Defendants’ MTD Reply	6
III. CONCLUSION	7

TABLE OF AUTHORITIES

CASES

<i>Access 4 All, Inc. v. Trump Int’l Hotel and Tower Condo.</i> , 458 F. Supp. 2d 160 (S.D.N.Y. 2006).....	4
<i>Am. Fed’n of State v. Bristol-Myers Squibb Co.</i> , 948 F. Supp. 2d 338 (S.D.N.Y. 2013).....	2
<i>Boca Raton Firefighters & Police Pension Fund v. Bahash</i> , 506 Fed. Appx. 32 (2d Cir. 2012).....	4
<i>Clarke v. Trans Union, LLC</i> , 2014 U.S. Dist. LEXIS 158552 (S.D.N.Y. Nov. 3, 2014)	4
<i>Ernst Haas Studio, Inc. v. Palm Press, Inc.</i> , 164 F.3d 110 (2d Cir. 1999).....	7
<i>Fonte v. Board of Managers of Continental Towers Condominium</i> , 848 F.2d 24 (2d Cir. 1988).....	4, 6
<i>Gerena v. Local 670 Stationary Eng’rs & Bldg. Servs. Union</i> , 2013 U.S. Dist. LEXIS 98820 (S.D.N.Y. July 10, 2013)	6
<i>Global Network Commc’ns., Inc. v. City of New York</i> , 458 F.3d 150 (2d Cir. 2006).....	1, 2, 5
<i>IHS Dialysis v. Davita, Inc.</i> , 2013 U.S. Dist. LEXIS 47532 (S.D.N.Y. Mar. 31, 2013)	2, 4
<i>In re Deutsche Bank AG Sec. Litig.</i> , 2011 U.S. Dist. LEXIS 93867 (S.D.N.Y. Aug. 19, 2011)	5
<i>In re Niaspan Antitrust Litig.</i> , 42 F. Supp. 3d 735 (E.D. Pa. 2014)	2
<i>In re UBS Auction Rate Sec. Litig.</i> , 2010 U.S. Dist. LEXIS 59024 (S.D.N.Y. June 10, 2010).....	5
<i>Muhammad v. Maduekwe</i> , 2015 U.S. Dist. LEXIS 141715 (S.D.N.Y. Oct. 15, 2015)	6
<i>Nakahata v. New York-Presbyterian Healthcare Sys.</i> , 723 F.3d 192 (2d Cir. 2013).....	2

<i>Revise Clothing, Inc. v. Joe's Jeans Subsidiary, Inc.</i> , 687 F. Supp. 2d 381 (S.D.N.Y. 2010).....	7
<i>Sacchi v. Verizon Online LLC</i> , 2015 U.S. Dist. LEXIS 48971 (S.D.N.Y. Apr. 14, 2015).....	7
<i>Sahu v. Union Carbide Corp.</i> , 548 F.3d 59 (2d Cir. 2008).....	6
<i>Shamir v. City of New York</i> , 2014 U.S. Dist. LEXIS 123774 (S.D.N.Y. Aug. 27, 2014).....	6
<i>Shamir v. City of New York</i> , 804 F.3d 553 (2d Cir. 2015).....	6

STATUTES

Fed. R. Civ. P. 56.....	4
Fed. R. Civ. P. 12.....	5
21 U.S.C. § 355a.....	6

I. INTRODUCTION

In their Motion to Dismiss (“MTD,” ECF No. 57), Defendants injected numerous extraneous facts and documents that are outside the scope of Direct Purchaser Plaintiffs’ (“Plaintiffs”) complaint. After Plaintiffs filed their opposition, Defendants submitted yet more extraneous evidence and exhibits with their reply brief (“MTD Reply,” ECF No. 76). The exhibits include private company documents that are not publicly available. Moreover, in their MTD Reply, Defendants raised legal arguments for the first time that Plaintiffs have not had an opportunity to rebut. Plaintiffs ask the Court to strike the extrinsic facts and new arguments asserted in Defendants’ MTD Reply, the Declaration of Kristen O’Shaughnessy dated February 12, 2016, as well as Exhibits 17-22 thereto. Additionally, Plaintiffs move for leave to file a sur-reply in further opposition to Defendants’ MTD, as attached as Exhibit 1 to the accompanying Declaration of Bruce E. Gerstein, to rebut Defendants’ new arguments.

II. ARGUMENT

A. Defendants’ Extraneous Declaration and Exhibits Should Be Stricken From the Record and Disregarded

In their MTD Reply, Defendants continue their practice of improperly relying on extraneous materials outside the scope of the complaint. “The purpose of Rule 12(b)(6) is to test, in a streamlined fashion, the formal sufficiency of the plaintiff’s statement of a claim for relief without resolving a contest regarding its substantive merits. The Rule thus assesses the legal feasibility of the complaint, but does not weigh the evidence that might be offered to support it.” *Global Network Commc’ns, Inc. v. New York*, 458 F.3d 150, 155 (2d Cir. 2006). But here Defendants have introduced extraneous material outside the scope of the pleadings in support of a 12(b)(6) motion, which another court recently recognized in another Hatch-Waxman case to be

“a plainly improper use of the [judicial notice] doctrine.” *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 754 (E.D. Pa. 2014).

This “plainly improper” use of judicial notice on a motion to dismiss is explained in *Global Network Commc'ns, Inc. v. New York*, 458 F.3d 150, 155 (2d Cir. 2006). There, the Court of Appeals determined that “the district court committed reversible error when, in ruling that the complaint failed to state a claim for which relief could be granted, it considered matters outside plaintiff's complaint,” including testimony from another case and determinations of a regulatory agency, since “all inferences from the complaint [are to] be construed in the plaintiffs favor,” and by “consider[ing] external material in its ruling, it relied on those materials to make a finding of fact that *controverted* the plaintiff's own factual assertions set out in its complaint.” 458 F.3d at 156 (emphasis in original).¹

Here, in their MTD, Defendants asserted extraneous facts and/or included documents about:

- the origin of Forest's decision to conduct pediatric testing (Forest claims that it conducted tests at FDA's request) (MTD at 7, 50);

¹ See also *Nakahata v. New York-Presbyterian Healthcare Sys.*, 723 F.3d 192, 203 (2d Cir. 2013) (reversing 12(b)(6) dismissal where “such dismissal was premised on matters outside the pleadings,” specifically, certain agreements that were exhibits to defendant's motion to dismiss, “and...therefore, inappropriate.”) (citing *Global Network Commc'ns*, 458 F.3d at 155); *IHS Dialysis v. Davita, Inc.*, 2013 U.S. Dist. LEXIS 47532, at *8-9 n.2 (S.D.N.Y. Mar. 31, 2013) (declining to take judicial notice of “two pending state court actions and a number of documents filed as exhibits in support of [a] motion to dismiss, and to thereafter rely on those materials to dismiss Plaintiffs' claims,” since “[w]hether or not the existence of the submitted documents are a proper subject of judicial notice, the facts contained therein, which Defendant seeks to offer for their truth, are most certainly not.”); *Am. Fed'n of State v. Bristol-Myers Squibb Co.*, 948 F. Supp. 2d 338, 353-54 n.15 (S.D.N.Y. 2013) (finding that assertions of counsel, findings of fact in other cases, and “statements about industry expectations and norms” are not “materials of which [the court] may properly take judicial notice.”).

- the reason Forest developed Namenda XR (Forest claims it developed Namenda XR to compete with other companies' once-a-day products) (MTD at 7);
- the underlying patent litigation and settlements (Forest claims that generic competitors settled because they did not want to risk a trial (MTD at 8); that Forest paid the generic competitors only "their litigation costs and attorneys' fees," (MTD at 8-9); that Forest won a claim construction decision and that its generic competitors decided to settle as a result (MTD at 43-46); and that the settlement agreements "properly accounted for the possibility of a pediatric exclusivity" (MTD at 50));
- the reasons physicians prescribed Namenda XR (whether physicians prescribed Namenda XR because they were coerced to switch or as a result of its "benefits," "caregiver acceptance," or "doctor excitement") (MTD at 11, 25-27, 32-33); and
- Forest's settlement with the New York Attorney General regarding whether Forest complied with the preliminary injunction and the impact of that alleged compliance (MTD at 13-14).

Now, in their MTD Reply, Defendants have again improperly injected still more external material, including documents upon which they ask this Court to make factual findings and legal determinations, including:

- a May 8, 2001 transcript of hearing of the United States Senate Committee on Health, Education, Labor, and Pensions. O'Shaughnessy Decl. Exhibit 17;
- a July 2, 2004 letter from the FDA to Pfizer responding to a citizen petition concerning 180-day first to file exclusivity under section 505(j)(5)(B)(iv). O'Shaughnessy Decl. Exhibit 18;
- a April 14, 2010 final approval letter from FDA to Dr. Reddy's Laboratories, Inc. for ANDA No. 90-048 for memantine hydrochloride tablets. O'Shaughnessy Decl. Exhibit 19;
- a June 5, 2015 letter from Forest Research Institute, Inc. to FDA concerning a license granted by Forest (owner of NDA No. 21-487) to Dr. Reddy's Labs (owner of ANDA No. 90-048) to market generic memantine hydrochloride tablets under ANDA No. 90-048 pursuant to the November 13, 2009 Settlement Agreement and License Agreement. O'Shaughnessy Decl. Exhibit 20;
- a July 1, 2015 letter from Forest Research Institute, Inc. to FDA concerning a license granted by Forest (owner of NDA No. 21-487) to Upsher-Smith Laboratories (owner of ANDA No. 90-043) to market generic memantine hydrochloride tablets under ANDA No. 90-043 pursuant to the September 8, 2009 Settlement Agreement and License Agreement. O'Shaughnessy Decl. Exhibit 21; and

- a July 31, 2015 final approval letter from FDA to Upsher-Smith Laboratories, Inc. (received by Upsher-Smith on August 6, 2015) for ANDA No. 90-043 for memantine hydrochloride tablets. O'Shaughnessy Decl. Exhibit 22.

Not only are Defendants' documents improper for consideration at the Motion to Dismiss stage, but Exhibits 20-22 are not even publicly-available documents. They are not available to anyone but the Defendants and the FDA. Such documents may or may not be produced by the Defendants in subsequent discovery but, in any event, cannot at this time be questioned, challenged, or properly analyzed by Plaintiffs or their experts. Plaintiffs need discovery to properly rebut Defendants' use of these documents.²

Courts have "two options when matters outside the pleadings are presented . . . the court may exclude the additional material and decide the motion on the complaint alone or it may convert the motion to one for summary judgment under Fed. R. Civ. P. 56[.]" *Fonte v. Bd. of Managers*, 848 F.2d 24, 25 (2d Cir. 1988). Courts routinely choose to strike purported facts and arguments beyond the scope of a complaint. *See Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 Fed. Appx. 32, 37 n.4 (2d Cir. 2012) (declining to take judicial notice of extrinsic material as improperly submitted and thus striking reference to them from reply brief); *Clarke v. Trans Union, LLC*, 2014 U.S. Dist. LEXIS 158552, at *14-15 (S.D.N.Y. Nov. 3, 2014) (McMahon, J.) (declining to convert since parties had not "engage[d] in meaningful discovery" and opting to "disregard any [extrinsic] submissions and decide the motion to dismiss on the merits of the pleadings alone." (quoting *Access 4 All, Inc. v. Trump Int'l Hotel and Tower Condo.*, 458 F. Supp. 2d 160, 165 (S.D.N.Y. 2006)); *IHS Dialysis*, 2013 U.S. Dist. LEXIS 47532 at *8-9 n.2 ("exclud[ing] all extrinsic materials submitted by the parties, and disregard[ing]

² Nevertheless, as Plaintiffs will show in their proposed sur-reply, even a cursory review of the exhibits, without more, illustrates that they actually support Plaintiffs' positions.

arguments based on materials outside the pleadings”); *In re Deutsche Bank AG Sec. Litig.*, 2011 U.S. Dist. LEXIS 93867, at *36 (S.D.N.Y. Aug. 19, 2011) (granting motion to strike a declaration and documents not referenced in plaintiffs’ complaint.); *In re UBS Auction Rate Sec. Litig.*, 2010 U.S. Dist. LEXIS 59024, at *50-51 (S.D.N.Y. June 10, 2010) (granting in part motion to strike and excluding “any portions of the declaration which set forth new facts, beyond the scope of the complaint, or legal arguments, both of which are not appropriate for consideration on a motion to dismiss.”).

This Court should thus follow the well-established principles of this District and the Second Circuit, and strike the extrinsic facts and arguments asserted in Defendants’ MTD Reply, and the Declaration of Kristen O’Shaughnessy dated February 12, 2016, as well as Exhibits 17-22 thereto.

B. If the Court Considers Defendants’ Extraneous Material, It Should Give Plaintiffs Notice of Its Intention to Convert Defendants’ Motion into One for Summary Judgment and an Opportunity to Submit Further Evidence, or a Rule 56(d) Declaration

For this Court to consider any of Defendants’ extrinsic assertions, it would have to convert Defendants’ 12(b)(6) motion into a motion for summary judgment. *Global Network Commc’ns*, at 154-55 (quoting Fed. R. Civ. P. 12(d) (“If . . . matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56.”)). Such conversion requires advance notice and an opportunity for Plaintiffs to confront the extraneous evidence. *See Global Network Commc’ns*, 458 F.3d at 155-56 (the “major problem that arises when a court considers matters extraneous to a complaint” is the “lack of notice to the plaintiff that outside matters would be examined”); *id.* at 155 (conversion requirement is intended to “deter[] trial courts from engaging in factfinding when ruling on a motion to dismiss and ensure[] that when a trial judge considers evidence dehors the

complaint, a plaintiff will have an opportunity to contest defendant's relied-upon evidence by submitting material that controverts it."). *See also Sahu v. Union Carbide Corp.*, 548 F.3d 59, 69-70 (2d Cir. 2008) (reversing grant of summary judgment from converted Rule 12 motion where plaintiffs did not receive notice because "plaintiffs could not have known whether the court would in fact consider [the extrinsic material], or would convert the motion into one for summary judgment in order to do so"); *Fonte*, 848 F.2d at 25 (when a court converts, it must "afford all parties the opportunity to present supporting material"); *Muhammad v. Maduekwe*, 2015 U.S. Dist. LEXIS 141715, at *4-5 (S.D.N.Y. Oct. 15, 2015) (McMahon, J.) (providing notice of intention to convert and ordering plaintiff to submit any additional material suitable for summary judgment by a date certain.); *Shamir v. New York*, 2014 U.S. Dist. LEXIS 123774, at *1 (S.D.N.Y. Aug. 27, 2014) (McMahon, J.) (same), *rev'd on other grounds*, 804 F.3d 553 (2d Cir. 2015); *Smith v. New York*, 2013 U.S. Dist. LEXIS 144122, at *6-7 (S.D.N.Y. Sept. 26, 2013) (McMahon, J.) (converting after "the parties ha[d] been given ample notice and opportunity to submit evidence"); *Gerena v. Local 670 Stationary Eng'rs & Bldg. Servs. Union*, 2013 U.S. Dist. LEXIS 98820, at *3 (S.D.N.Y. July 10, 2013) (McMahon, J.) (providing thirty-days' notice of conversion to provide an opportunity for plaintiff to submit evidence).

Thus, if this Court intends to convert the MTD to a summary judgment motion, Plaintiffs respectfully request advance notice and an opportunity to respond.

C. Plaintiffs Should Be Granted Leave to File a Sur-Reply to Defendants' MTD Reply

Not only do Defendants rely on materials outside the pleadings, but in their MTD Reply, they make new legal arguments to which Plaintiffs have not had an opportunity to respond. Specifically, Defendants ignore the text of 21 U.S.C. § 355a(c)(1)(B)(ii), which governs the application of pediatric exclusivity to ANDAs filed with Paragraph IV certifications, to argue,

for the first time, that the FDA interprets the statute contrary to the statute's plain meaning and differently than in publicly-available interpretations.

For example, Defendants argue for the first time that generics that already have final approval are further required to provide the FDA with proof of when they were licensed by the brand to launch. MTD Reply at 19. Defendants also make new arguments regarding Congressional intent (*id.* at 14); and the effect of “legislative silence” (to the extent such “silence” existed) (*id.* at 17). Plaintiffs wish to address Defendants’ new legal arguments and statutory interpretations and hereby request leave to file a sur-reply, appended as Exhibit 1 to the Declaration of Bruce E. Gerstein, submitted herewith. *See Ernst Haas Studio, Inc. v. Palm Press, Inc.*, 164 F.3d 110, 112 (2d Cir. 1999) (“An attempt is made in the Reply Brief to supply what was conspicuously omitted in the main Brief . . . However, new arguments may not be made in a reply brief[.]”); *Sacchi v. Verizon Online LLC*, 2015 U.S. Dist. LEXIS 48971, at *1-2 n.1 (S.D.N.Y. Apr. 14, 2015) (leave to submit a surreply appropriate to rebut arguments made for first time in a reply brief); *Revise Clothing, Inc. v. Joe's Jeans Subsidiary, Inc.*, 687 F. Supp. 2d 381, 387 (S.D.N.Y. 2010) (same).

Defendants’ new legal arguments are an attempt to cast doubt on the legal sufficiency of Plaintiffs’ claims. Plaintiffs request an opportunity to rebut them.

III. CONCLUSION

For the reasons sated above, Plaintiffs respectfully request that this Court strike (or disregard) Defendants’ Declaration of Kristen O’Shaughnessy dated February 12, 2016, Exhibits 17-22 thereto and arguments based on those exhibits, and grant leave to Plaintiffs to file a sur-reply memorandum in further opposition to Defendants’ MTD, substantially in the form attached to the accompanying Declaration of Bruce E. Gerstein as Exhibit 1.

Dated: February 19, 2016

Respectfully Submitted:

/s/Bruce E. Gerstein
Bruce E. Gerstein

GARWIN GERSTEIN & FISHER LLP

Bruce E. Gerstein
Joseph Oppen
Dan Litvin
Kimberly M. Hennings
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055
Fax: (212) 764-6620
bgerstein@garwingerstein.com

SMITH SEGURA & RAPHAEL, LLP

David C. Raphael, Jr.
Erin R. Leger
3600 Jackson Street, Suite 111
Alexandria, LA 71303
Tel: (318) 445-4480
Fax: (318) 487-1741
draphael@ssrllp.com

ODOM & DES ROCHES, L.L.P.

Stuart E. Des Roches
Andrew W. Kelly
650 Poydras Street, Suite 2020
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078
stuart@odrlaw.com

HEIM PAYNE & CHORUSH, LLP

Russ Chorush
Miranda Jones
600 Travis, Suite 6710
Houston, TX 77002
Tel: (713) 221-2000
Fax: (713) 221-2021
rchorush@hpcellp.com

*Counsel for J M Smith Corporation d/b/a Smith
Drug Company and the Proposed Class*

FARUQI & FARUQI, LLP

Elizabeth A. Silva (No. ES-2011)
685 Third Avenue, 26th Floor
New York, NY 10017
Tel: (212) 983-9330
Fax: (212) 983-9331
esilva@faruqilaw.com

FARUQI & FARUQI, LLP

Peter Kohn
Joseph T. Lukens
Neill W. Clark
101 Greenwood Avenue, Suite 600
Jenkintown, PA 19046
Tel: (215) 277-5770
Fax: (215) 277-5771
pkohn@faruqilaw.com
jlukens@faruqilaw.com
nclark@faruqilaw.com

BERGER & MONTAGUE, P.C.

David F. Sorensen
1622 Locust Street
Philadelphia, PA 19103
Tel: (215) 875-4675
Fax: (215) 875-4604
dsorensen@bm.net

*Counsel for Rochester Drug Co-Operative, Inc. and
the Proposed Class*

CERTIFICATE OF SERVICE

I hereby certify that on February 19, 2016, I electronically filed the above memorandum by CM/ECF system.

Respectfully submitted

/s/ Bruce E. Gerstein
Bruce E. Gerstein